

## Session 5:

# Saudi FDA Unique Device Identification (UDI)



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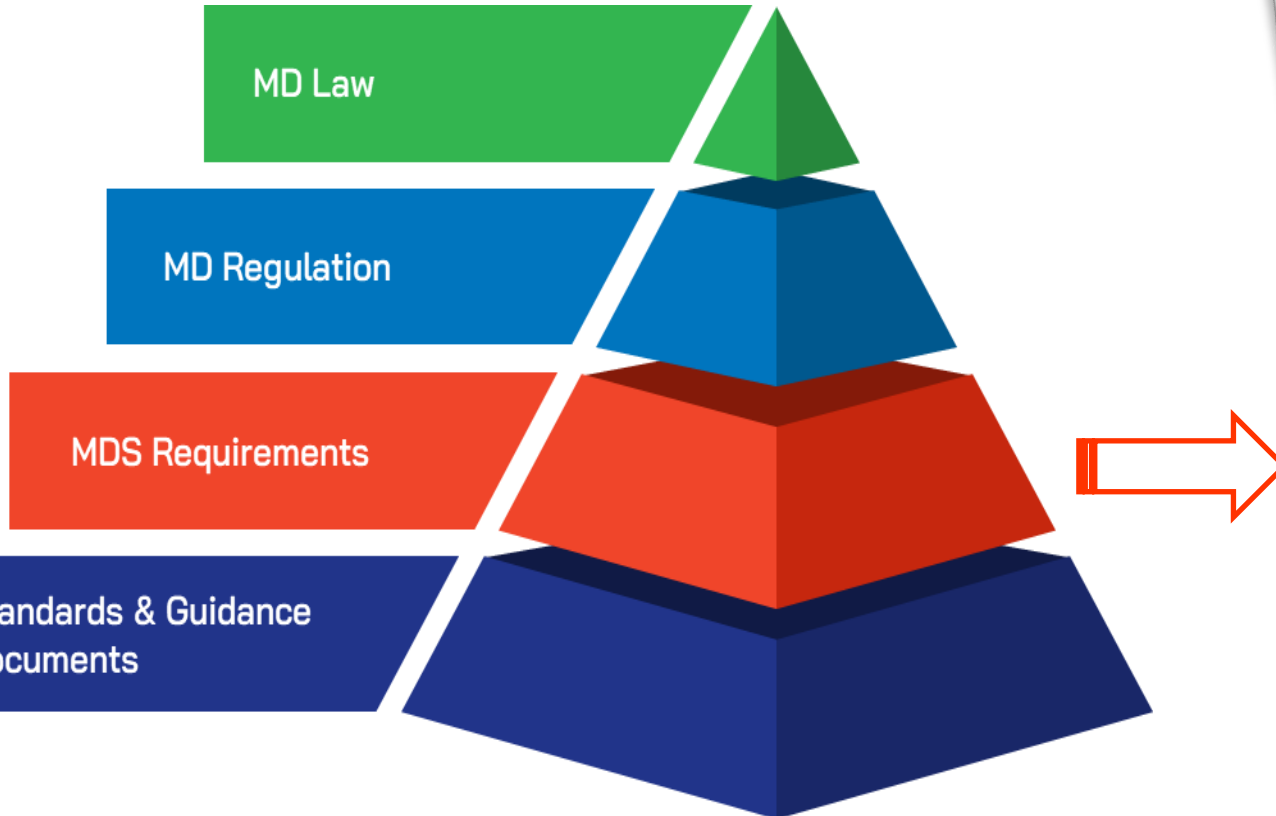


## AGENDA

- ☐ Introduction.
- ☐ SFDA -UDI Requirements & Submission steps.
- ☐ Summary of the experience and the most important considerations for the future



# SFDA MD Regulation Framework





## Compliance Dates and The current progress

Compliance Timeframe	
Launching the UDI database and starting optional registration for all type of devices	1 <sup>st</sup> October 2020
Risk Class	Compliance date
Class B & C (Medium risk) Class D (High risk)	1 <sup>st</sup> September 2023
Class A (Low risk)	1 <sup>st</sup> September 2024

### Submitted UDI Records ( Aug. 2025 )

#of Devices

**446703**

#of Manufacturers

**1797**

## Scope

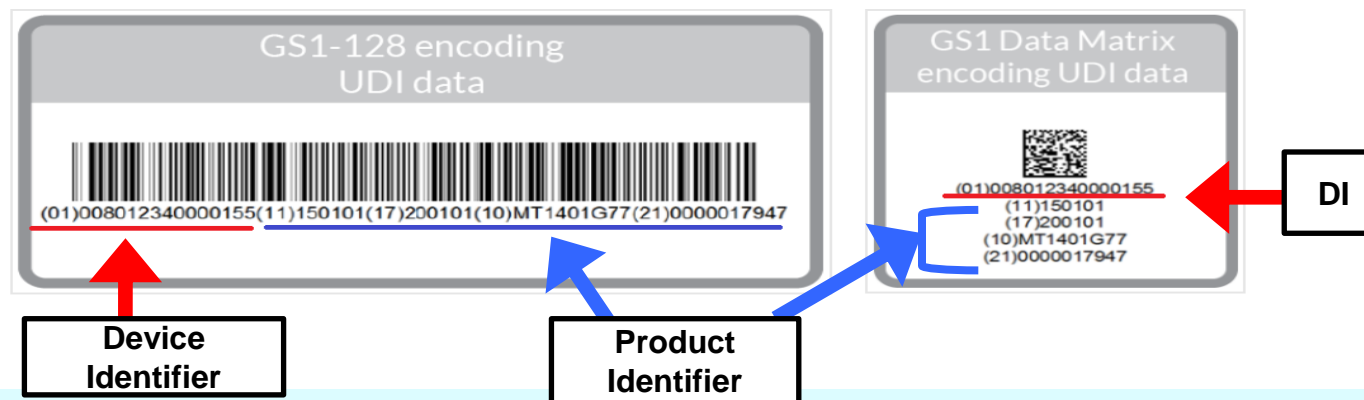
- ✓ All medical devices & accessories,
- ✓ The **manufacturer**, or its **authorized representative**, shall submit and maintain the appropriate data in UDI database

## General UDI Requirements include:

- ✓ Recognized issuing Agencies: GS1, HIBCC and ICCBBA
- ✓ The UDI label shall contain two parts: the UDI-DI and the UDI-PI(s).
- ✓ UDI-PI shall include: lot number, serial number, software identification, or expiration (use by) date
- ✓ The UDI shall be readable during normal use and throughout the intended life of the device

## UDI in Label

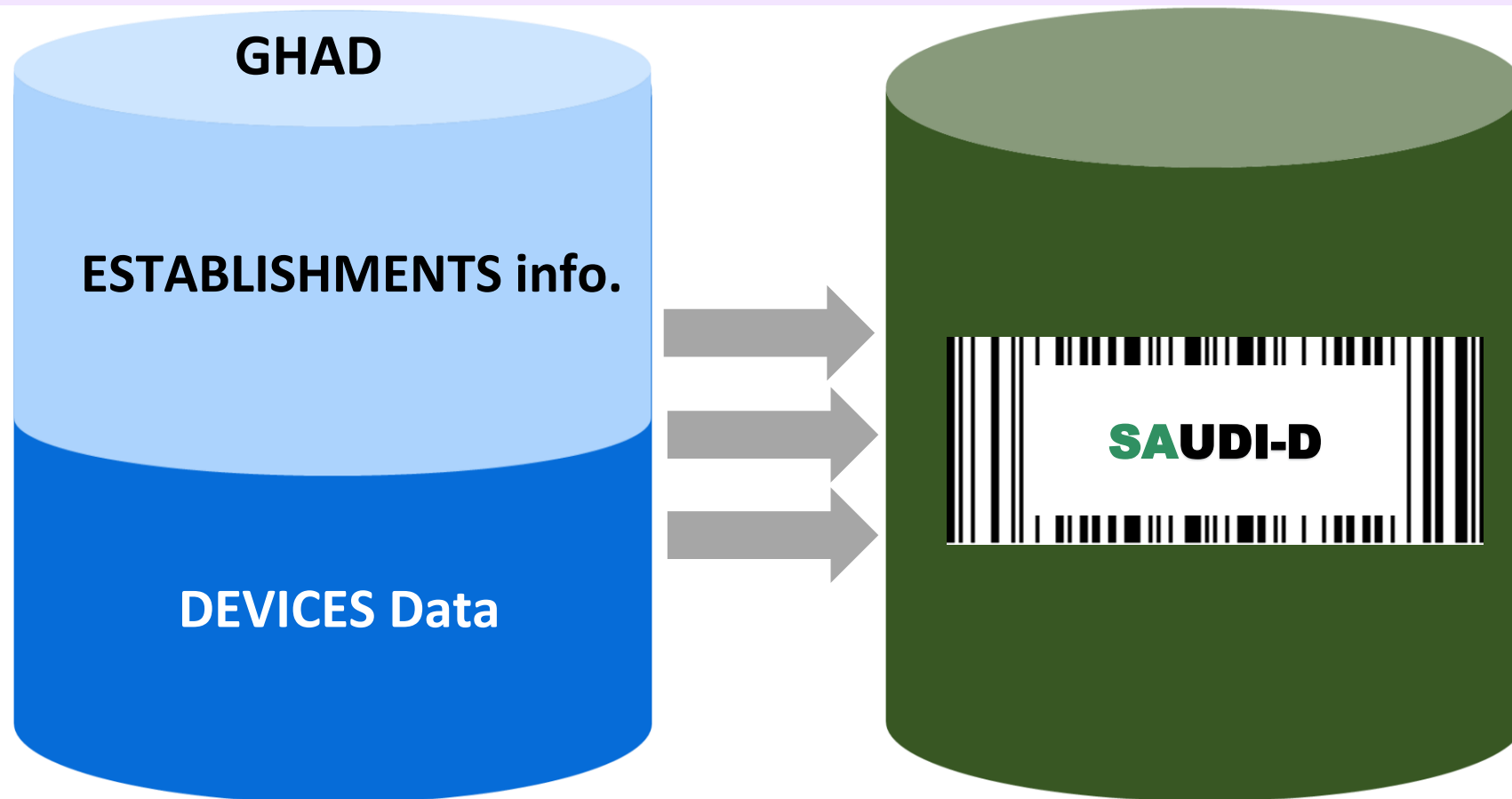
- ✓ The UDI must be presented in two forms on the device label and higher levels of packaging:
- 1. **Human Readable Interpretation (HRI):** Easily readable plain-text format.
- 2. **Automatic Identification and Data Capture (AIDC) Technology:** Such as barcodes (linear or 2D) or RFID, enabling automated scanning and data capture.



## SAUDI-DI Database

- The data shall be available in SAUDI-DI database at the time the device is placed on the market.
- Device Records need to be checked and maintained periodically (at least annually) by the manufacturer or its authorized representative
  - ✓ Revisions shall be made within 10 days when the data changes
  - ✓ ensure the data is accurate and consistent with data submitted to GHAD system modules

## SFDA Systems





# Unique Device Identifications

sign in

By entering a valid listing number, **all relevant information will be retrieved from Marketing Authorization database.**

<b>Listing Number</b>	<b>Authorization Number</b>
ME0000000091SFDAA00008	MDMA-1-2021-0053
<b>Brand Name</b>	<b>Device Type</b>
test Product by Belal	Medical Device
<b>Manufacturer Name</b>	<b>Device Classification</b>
Test Manufacturer by Belal	Class III
<b>Manufacturer Number</b>	<b>Device Description</b>
ME0000000091	12345678900
<b>Product Name</b>	<b>sterile Device</b>
test Product by Belal	-
	<b>Home Use</b>
	No



**Primary UDI-DI** on the device's primary label, which consider a primary key in the database and to which other DIs are linked to it

**UDI-DI issuing agency** is selected from drop-down .

**Quantity** is number of units in this device or package

Production identifiers \*

- ☒ Lot number.
- ☐ Serial number.
- ☒ Expiration (use by) date.
- ☒ Manufacturing date.
- ☐ Software version.

☐ Is it a software?

UDI-DI Device Information

Mandatory Fields \*

Primary UDI-DI as labeled ⓘ \*

1234567891011121314151617181920TR

UDI-DI issuing agency \*

ICCBBA

Quantity \*

12

Unit of Use UDI-DI ⓘ

337799123654



## Package UDI-DI

- Package Information
- Add levels of the package hierarchy starting from the bigger level.



**Lower level**

**bigger level**

### Device Package Information

**Mandatory Fields \***

The device is shipped in only one level of package (primary package)?

☐ Yes  
☒ No

DI for highest level ⓘ \*

Package Type

bag


Quantity per package

1

☐ DI of the next lower package.

## Summary View of Submission

Upon submission, the summary of the record is displayed.



Home
Device List
User Guide
FAQs
Sign out
Hello mabusaa@netways.c

General information
Reference# 39

Listing Number

ML0000000290SFDAA00007

Authorization Number

GHTF-2020-1639

Accessory Brand Name

ACEG

Device Classification

Class IIa

Accessory Model Number

0012

Device Type

Medical Device

Manufacturer Name

Saudi Mais Co. For Medical Products

Device Information

Unit of Use DI

337799123654

Is it a Software?

No

UDI Type

ICCBBA

Production Identifiers

☒ Lot number
☐ Expiration (Use by) date
☐ Manufacturing date

Quantity

12

The Device Considered as

Kit or Procedure packs

Package DI for highest level

(10)456778

Quantity Per Package

6

Package Type

Carton

DI of the next lower package

DI	Type	Quantity per package
(02)48586	Box	100

Device characteristics

Catalog Number

3456

Critical warnings

Don't use with water, Do not wrap the tube

Clinical size

> 10cm  
> 5cm

Storage and handling conditions

room temperature,

Is the device labeled as "containing natural rubber latex or dry natural rubber" ?

Yes


Restricted number of reuses

0

Is the device labeled as "Not made with natural rubber latex" ?

Yes

MRI safety status



الهيئة العامة للغذاء والدواء  
Saudi Food & Drug Authority



## Bulk upload

- Bulk upload for submitting many records in a single Excel sheet
- All data will be automatically saved and displayed within the Devices records list.
- Any wrong data should be corrected individually through the update action.

The screenshot displays the SFDA portal's 'Devices List' page. A modal window titled 'Upload multiple devices' is open, allowing users to choose a template (currently 'single use + single item') and download it. A 'Choose File' button is present, with a note that no file has been chosen. A warning states that the number of devices cannot exceed 150. A 'Submit devices' button is at the bottom right of the modal. The background shows a dashboard with statistics like '#of Devices', '#of Accessories', and 'Manufacturers', along with a search bar and a 'Bulk upload' button.

## Device List page

### Icon Actions

- **Add Device** –to start a new record
- **Column Visibility** – to select the columns displayed
- **Excel** – to export a spreadsheet of records

### Search Field

#of Devices	6	#of Primary DIs	0	#of Units of use DIs	6
#of Accessories	1	#of Drafts	0	#of Manufacturers	5

+ Add Device
Devices List: 6 device/s

Column visibility
Excel
Search:

reference#	Manufacturer Name	Listing Number	Brand Name	Primary DI	Unit of use DI	Added Date
39						2020-08-29
1050						2020-09-28
1051						2020-09-30
1058						2020-10-20

## Summary of the experience and the most important considerations for the future

- The implementation of UDI is a crucial initiative that highlights the **commitment to a safe, transparent, and efficient** medical device ecosystem.
- By establishing clear regulatory requirements ,providing a central database, and implementing a phased compliance approach, the SFDA is actively **enhancing patient safety, improving product traceability**, and bolstering the integrity of the medical device supply chain.
- The Saudi UDI framework is **aligned** with global guidelines and initiatives.
- The **continued collaboration** among manufacturers, healthcare providers, and the SFDA will be crucial in realizing the full potential of UDI, ultimately contributing to a healthier future for the people of Saudi Arabia.



## Summary of the experience and future considerations

➤ **Ongoing efforts** are crucial to address potential challenges:

- Awareness and Education
- Systems Integration
- Data Quality and Accuracy
- Technological Adoption
- Global Harmonization and Continued collaboration.

**Thank You**

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